Pancreas Transplant Recipient Registration (TRR) Record Field Descriptions

The Transplant Recipient Registration (TRR) records are generated and available immediately after a transplant event is reported through the recipient feedback process in Waitlist. A TRR will also be generated in the case of a living donor transplant, where a recipient was added through the donor feedback process in Tiedi®. The Transplant Recipient Registration (TRR) record is completed by the transplant center performing the transplant. The registration and hospital discharge follow-up information is combined in this record.

Complete the TRR at hospital discharge or six weeks post transplant, whichever is first. If the recipient is still hospitalized at six weeks post transplant, provide the most recent information available regarding the recipient's progress.

View OPTN/UNOS Policy on Data Submission Requirements for additional information.

To correct information that is already displayed on an electronic record, call 1-800-978-4334.

Recipient Information

Name: Verify the last name, first name and middle initial of the transplant recipient is correct. If the information is incorrect, corrections may be made on the recipient's TCR record.

DOB: Verify the displayed date is the recipient's date of birth. If the information is incorrect, corrections may be made on the recipient's TCR record.

SSN: Verify the recipient's social security number is correct. If the information is incorrect, contact the Help Desk at 1-800-978-4334.

Gender: Verify the recipient's gender is correct. If the information is incorrect, corrections may be made on the recipient's TCR record.

HIC: Verify the 9 to 11 character Health Insurance Claim number for the recipient indicated on the recipient's most recently updated TCR record is correct. If the recipient does not have a HIC number, you may leave this field blank.

Tx Date: Verify the displayed transplant date is the date of the beginning of the first anastomosis. If the operation started in the evening and the first anastomosis began early the next morning, the transplant date is the date that the first anastomosis began. The transplant is considered complete when the cavity is closed and the final skin stitch/staple is applied. The transplant date is indicated immediately after a transplant event is reported through the recipient feedback process in Waitlist and in the case of a living donor transplant, where a recipient was added through the donor feedback process in Tiedi.

State of Permanent Residence: Select the name of the state, of the recipient's permanent address, at the time of transplant.

Permanent Zip: Enter the recipient's zip code, of their permanent address, at the time of transplant.

Provider Information

Recipient Center: The recipient center will display. Verify the transplant center name and the center code, and the provider number, (6-character Medicare identification number of the hospital where the transplant recipient was transplanted) are correct.

Surgeon Name: Enter the name of the primary surgeon, who performed the transplant operation, and under whose name the transplant is billed.

NPI #: Enter the 10-character CMS (Center for Medicare and Medicaid Services, formerly HCFA) assigned National Provider Identifier of the transplant physician. Your hospital billing office may be able to obtain this number for you.

Donor Information

UNOS Donor ID #: The UNOS Donor ID number, reported in the Recipient Feedback, will display. Each potential donor is assigned an identification number by OPTN/UNOS. This ID number corresponds to the date the donor information was entered into the OPTN/UNOS computer system.

Donor Type: The donor type, reported in the Recipient Feedback, will display. Verify the recipient's donor type is correct. If the information is incorrect, contact the Help Desk at 1-800-978-4334.

Deceased indicates the donor was not living at the time of donation.
Living indicates the donor was living at the time of donation.

Patient Status

Primary Diagnosis: Select the primary diagnosis **for the disease requiring a transplant** for this recipient at the time of transplant. If the recipient has had a previous transplant for the same organ type, enter **Retransplant/Graft Failure** as the primary diagnosis for that organ. If **Other, Specify** is selected, enter the primary diagnosis in the space provided.

Date of: Report or Death: Enter the date the hospital reported the recipient as living, retransplanted (when the data was obtained prior to the recipient's discharge) or the date of the recipient's death, using the standard 8-digit numeric format of MM/DD/YYYY.

Patient Status: Select the appropriate status for this recipient. If **Dead** is selected, indicate the cause of death.

Living
Dead
Retransplanted

Primary Cause of Death: If the Patient Status is **Dead**, select the patient's cause of death. If an **Other** code is selected, enter the other cause of death in the space provided.

Contributory Cause of Death: If the Patient Status is **Dead**, select the patient's contributory cause of death. If an **Other** code is selected, enter the other cause of death in the space provided.

Contributory Cause of Death: If the Patient Status is **Dead**, select the patient's contributory cause of death. If an **Other** code is selected, enter the other cause of death in the space provided.

Note: If the patient is being retransplanted, access the patient's last record for their previous transplant and select **Retransplanted** in the **Patient Status** field. This will stop the generation of TRF records associated with the previous transplant.

Transplant Hospitalization:

Date of Admission to Tx Center: Enter the date the recipient was admitted to the transplant center, using the standard 8-digit MM/DD/YYYY format.

Date of Discharge from Tx Center: Enter the date the recipient was released to go home, using the standard 8-digit MM/DD/YYYY format. The recipient's hospital stay includes total time spent in different units of the hospital, including medical and rehab. This information is not required in the TRR record, but if entered here, it will automatically fill in the future TRF records. It is required in the TRF record.

Note: Leave this field blank if the recipient was removed from the waiting list with a code of 21, indicating the recipient died during the transplant procedure.

Was patient hospitalized during the last 90 days prior to the transplant admission? If the recipient was hospitalized during the last 90 days prior to transplant admission, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is optional.

Medical Condition at time of transplant: Select the choice that best describes the recipient's condition and location just prior to the time of transplant.

In Intensive Care Unit
Hospitalized Not in ICU
Not Hospitalized

Functional Status: Select the choice that best describes the recipient's functional status just prior to the time of transplant.

Note: The Karnofsky Index will display for adults aged 18 and older.

10% - Moribund, fatal processes progressing rapidly
20% - Very sick, hospitalization necessary: active treatment necessary
30% - Severely disabled: hospitalization is indicated, death not imminent
40% - Disabled: requires special care and assistance
50% - Requires considerable assistance and frequent medical care
60% - Requires occasional assistance but is able to care for needs
70% - Cares for self: unable to carry on normal activity or active work
80% - Normal activity with effort: some symptoms of disease
90% - Able to carry on normal activity: minor symptoms of disease
100% - Normal, no complaints, no evidence of disease
Unknown

Note: The Lansky Scale will display for pediatrics aged 1 to 17.

10% - No play; does not get out of bed
20% - Often sleeping; play entirely limited to very passive activities
30% - In bed; needs assistance even for quiet play
40% - Mostly in bed; participates in quiet activities
50% - Can dress but lies around much of day; no active play; can take part in quiet play/activities
60% - Up and around, but minimal active play; keeps busy with quieter activities
70% - Both greater restriction of and less time spent in play activity
80% - Active, but tires more quickly
90% - Minor restrictions in physically strenuous activity
100% - Fully active, normal
Not Applicable (patient < 1 year old)
Unknown

Note: This evaluation should be in comparison to the person's normal function, indicating how the patient's disease has affected their normal function.

Physical Capacity: (Complete for recipients older than 18 years of age.) Select the choice that best describes the recipient's physical capacity at the time of listing. If the recipient's **Medical Condition** indicates they are hospitalized, select **Not Applicable (hospitalized)**. This field is optional for **adult** recipients only.

No Limitations
Limited Mobility
Wheelchair bound or more limited
Not Applicable (hospitalized)
Unknown

Physical Capacity is the ability to perform bodily activities such as walking, dressing, bathing, grooming, etc.

Cognitive Development: (Complete for recipients 18 years of age or younger.) Select the choice that best describes the recipient's cognitive development at the time of listing.

Definite Cognitive Delay/Impairment (verified by IQ score <70 or unambiguous behavioral observation)

Probable Cognitive Delay/Impairment (not verified or unambiguous but more likely than not, based on behavioral observation or other evidence)

Questionable Cognitive Delay/Impairment (not judged to be more likely than not, but with some indication of cognitive delay/impairment such as expressive/receptive language and/or learning difficulties)

No Cognitive Delay/Impairment (no obvious indicators of cognitive delay/impairment)

Not Assessed

Motor Development: (Complete for recipients 18 years of age or younger.) Select the choice that best describes the recipient's motor development at the time of listing.

Definite Motor Delay/Impairment (verified by physical exam or unambiguous behavioral observation)

Probable Motor Delay/Impairment (not verified or unambiguous but more likely than not, based on behavioral observation or other evidence)

Questionable Motor Delay/Impairment (not judged to be more likely than not, but with some indication of motor delay/impairment)

No Motor Delay/Impairment (no obvious indicators of motor delay/impairment)

Not Assessed

Working for income? (Complete for recipients 19 years of age or older.) If the recipient is working for income just prior to the time of transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**.

If Yes: If **Yes** is selected, indicate the recipient's working status. (This field is optional for **adult** recipients only.)

Working Full Time
Working Part Time due to Demands of Treatment
Working Part Time due to Disability
Working Part Time due to Insurance Conflict
Working Part Time due to Inability to Find Full Time Work
Working Part Time due to Patient Choice
Working Part Time Reason Unknown
Working, Part Time vs. Full Time Unknown

If No, Not Working Due To: If **No** is selected, indicate the reason why the recipient is not working at the time of listing. (This field is optional for **adult** recipients only.)

Disability - A physical or mental impairment that interferes with or prevents a recipient from working (e.g. arthritis, mental retardation, cerebral palsy, etc).

Demands of Treatment - An urgent medical treatment that prevents a recipient from working (e.g. Dialysis).

Insurance Conflict - Any differences between a recipient and insurance company that prevents them from working.

Inability to Find Work - The lack of one's ability to find work. (e.g. lack of transportation, work experience, over qualification, unavailable work, etc.)

Patient Choice - Homemaker - A recipient who chooses to manage their own household, instead of performing work for pay.

Patient Choice - Student Full Time/Part Time - A recipient who is enrolled and/or participating in college.

Patient Choice - Retired - A recipient who no longer has an active working life such as an occupation, business or office job.

Patient Choice - Other - Any reason not listed above that would prevent a recipient from working.

Not Applicable - Hospitalized - Select only if the patient's Medical Condition indicates they are in the hospital.

Unknown

Academic Progress: (Complete for recipients 18 years of age or younger.) Select the choice that best describes the recipient's academic progress just prior to the time of transplant.

Within One Grade Level of Peers
Delayed Grade Level
Special Education
Not Applicable <5 years old
Status Unknown

Academic Activity Level: (Complete for recipients 18 years of age or younger.) Select the choice that best describes the recipient's academic activity level just prior to the time of transplant. If the recipient is less than 5 years old or has graduated from high school, select **Not Applicable < 5 years old/High School graduate**.

Full academic load
Reduced academic load
Unable to participate in academics due to disease or condition
Not Applicable <5 years old/High School graduate
Status Unknown

Source of Payment:

Primary: Select as appropriate to indicate the recipient's source of primary payment (largest contributor) for the transplant.

Private insurance refers to funds from agencies such as Blue Cross/Blue Shield, etc. It also refers to any worker's compensation that is covered by a private insurer.

Public insurance - Medicaid refers to state Medicaid funds.

Public insurance - Medicare FFS (Fee-for-Service) refers to funds from the government in which doctors and other health care providers are paid for each service provided to a recipient. For additional information about Medicare, see http://www.medicare.gov/Choices/Overview.asp.

Public insurance - Medicare & Choice (also known as Medicare Managed Care) refers to funds from the government in which doctors and other health care providers are paid for each service provided to a recipient, along with additional benefits (i.e., coordination of care or reducing-out-of-pocket expenses. Sometimes a recipient may receive additional benefits such as prescription drugs.). For additional information about Medicare, see http://www.medicare.gov/Choices/Overview.asp.

Public insurance - CHIP (Children's Health Insurance Program)

Public insurance - Department of VA refers to funds from the Veterans Administration.

Public insurance - Other government

Self indicates that the recipient will pay for the cost of transplant.

Donation indicates that a company, institution, or individual(s) donated funds to pay for the transplant and care of the recipient.

Free Care indicates that the transplant hospital will not charge recipient for the costs of the transplant operation.

Foreign Government, Specify refers to funds provided by a foreign government (Primary only) Specify foreign country in the space provided.

Secondary: Select check as appropriate to indicate the recipient's source of secondary payment. This field is optional.

Private insurance refers to funds from agencies such as Blue Cross/Blue Shield, etc. It also refers to any worker's compensation that is covered by a private insurer.

Public insurance - Medicaid refers to state Medicaid funds.

Public insurance - Medicare FFS (Fee-for-Service) refers to funds, from the government in which doctors and other health care providers are paid for each service provided to a recipient. For additional information about Medicare, see http://www.medicare.gov/Choices/Overview.asp.

Public insurance - Medicare & Choice (also known as Medicare Managed Care) refers to funds from the government in which doctors and other health care providers are paid for each service provided to a recipient, along with additional benefits (i.e., coordination of care or reducing-out-of-pocket expenses. Sometimes a recipient may receive additional benefits such as prescription drugs). For additional information about Medicare, see http://www.medicare.gov/Choices/Overview.asp.

Public insurance - CHIP (Children's Health Insurance Program)

Public insurance - Other government

Self indicates that the recipient will pay for the cost of transplant.

Donation indicates that a company, institution, or individual(s) donated funds to pay for the transplant and care of the recipient.

Free Care indicates that the transplant hospital will not charge the recipient for the costs of the transplant operation.

None - Select if the recipient does not have a secondary source of payment.

Clinical Information : Pretransplant

Date of Measurement: (Complete for recipients 18 years of age or younger.) Enter the date, using the 8-digit format of MM/DD/YYYY, the recipient's height and weight were measured.

Height: Enter the height of the recipient at the time of discharge in the appropriate space, in feet and inches or centimeters. If the recipient's height is unavailable, select the appropriate status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**). For recipients 18 years old or younger at the time of listing, UNet will generate and display calculated percentiles based on the 2000 CDC growth charts.

Weight: Enter the weight of the recipient at the time of discharge in the appropriate space, in pounds or kilograms. If the recipient's weight is unavailable, select the appropriate status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**). For recipients 18 years old or younger at the

time of listing, UNet will generate and display calculated percentiles based on the 2000 CDC growth charts.

BMI (Body Mass Index): The recipient's BMI will display. For recipients 18 years old or younger, at the time of listing, UNet will generate and display calculated percentiles based on the 2000 CDC growth charts.

> **Percentiles** are the most commonly used clinical indicator to assess the size and growth patterns of individual children in the United States. Percentiles rank the position of an individual by indicating what percent of the reference population the individual would equal or exceed (i.e. on the weight-for-age growth charts, a 5 year-old girl whose weight is at the 25th percentile, weighs the same or more than 25 percent of the reference population of 5-year-old girls, and weighs less than 75 percent of the 5-year-old girls in the reference population). For additional information about CDC growth charts, see http://www.cdc.gov/.

Previous Transplants: The three most recent transplant(s), indicated on the recipient's validated Transplant Recipient Registration (TRR) record(s), will display. Verify all previous transplants listed by organ type, transplant date and graft failure date.

Note: The three most recent transplants on record for this recipient will be displayed for verification. If there are any prior transplants that are not listed here, contact the UNet Helpdesk at 1-800-978-4334 or unethelpdesk@unos.org to determine if the transplant event is in the database.

Pretransplant Dialysis: If the recipient was on maintenance dialysis before transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**.

> **If Yes, Date First Dialyzed:** If the recipient was on maintenance dialysis before transplant, enter the date that the recipient first began dialysis. If the date is unavailable, select the appropriate status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**).

Average Daily Insulin Units: Enter the recipient's average daily insulin in units. If the value is unavailable, select the appropriate status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**).

Serum Creatinine at Time of TX: Enter the serum creatinine at the time of transplant in mg/dl. If the value is unavailable, select the appropriate status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**).

Viral Detection:

> **HIV Serostatus:** Select the serology results from the drop-down list.
>
> > **Positive**
> > **Negative**
> > **Not Done**
> > **UNK/Cannot Disclose**
> >
> > Definition: Human Immunodeficiency Virus - Any of several retroviruses and especially HIV-1 that infect and destroy helper T cells of the immune system causing the marked reduction in their numbers that is diagnostic of AIDS.
>
> **CMV IgG:** Select the serology results from the drop-down list.
>
> > **Positive**
> > **Negative**
> > **Not Done**
> > **UNK/Cannot Disclose**
> >
> > Definition: Cytomegalovirus - A herpesvirus (genus Cytomegalovirus) that causes cellular enlargement and formation of eosinophilic inclusion bodies especially in the nucleus and that acts as an opportunistic infectious agent in immunosuppressed conditions (as AIDS).

CMV IgM: Select the serology results from the drop-down list.

Positive
Negative
Not Done
UNK/Cannot Disclose

Definition: Cytomegalovirus - A herpesvirus (genus Cytomegalovirus) that causes cellular enlargement and formation of eosinophilic inclusion bodies especially in the nucleus and that acts as an opportunistic infectious agent in immunosuppressed conditions (as AIDS).

HBV Core Antibody: Select the serology results from the drop-down list.

Positive
Negative
Not Done
UNK/Cannot Disclose

Definition: Hepatitis B Virus - A sometimes fatal hepatitis caused by a double-stranded DNA virus (genus Orthohepadnavirus of the family Hepadnaviridae) that tends to persist in the blood serum and is transmitted especially by contact with infected blood (as by transfusion or by sharing contaminated needles in illicit intravenous drug use) or by contact with other infected bodily fluids (as during sexual intercourse) -- also called serum hepatitis.

HBV Surface Antigen: Select the serology results from the drop-down list.

Positive
Negative
Not Done
UNK/Cannot Disclose

Definition: Hepatitis B Virus - A sometimes fatal hepatitis caused by a double-stranded DNA virus (genus Orthohepadnavirus of the family Hepadnaviridae) that tends to persist in the blood serum and is transmitted especially by contact with infected blood (as by transfusion or by sharing contaminated needles in illicit intravenous drug use) or by contact with other infected bodily fluids (as during sexual intercourse) -- also called serum hepatitis.

HCV Serostatus: Select the serology results from the drop-down list.

Positive
Negative
Not Done
UNK/Cannot Disclose

Definition: Hepatitis C Virus - A disease caused by a flavivirus that is usually transmitted by parenteral means (as injection of an illicit drug, blood transfusion, or exposure to blood or blood products) and that accounts for most cases of non-A, non-B hepatitis.

EBV Serostatus: Select the serology results from the drop-down list.

Positive
Negative
Not Done
UNK/Cannot Disclose

Definition: (Epstein-Barr Virus) - A herpesvirus (genus Lymphocryptovirus) that causes infectious mononucleosis and is associated with Burkitt's lymphoma and nasopharyngeal carcinoma -- abbreviation EBV; called also EB virus.

Malignancies between listing and transplant: If recipient had any malignancies between listing and transplant, select **Yes**. If the recipient has not had any malignancies, select **No**. If **Yes** is selected, indicate type of malignancy. If the recipient had a malignancy, but the type of malignancy is not listed, select **Other, specify** and enter the name of the malignancy in the space provided.

Skin Melanoma
Skin Non-Melanoma
CNS Tumor
Genitourinary
Breast
Thyroid
Tongue/Throat/Larynx
Lung
Leukemia/Lymphoma
Liver
Other, specify

Note: This question is NOT applicable for patients receiving living donor transplants who were never on the waiting list.

Clinical Information : Transplant Procedure

Multiple Organ Recipient: If the recipient received other organs, reported on the Recipient Feedback, they will display. If the recipient didn't receive any other organs at this time, **None** is displayed. Verify the other organs, transplanted at this time, are correct. If incorrect, contact the Help Desk.

Were extra vessels used in the tx procedure: If extra vessels (vascular allografts) were used in the transplant procedure, as indicated on the Waitlist Removal, **YES** displays.

Vessel Donor ID: The **Donor ID** entered on the Waitlist Removal displays.

Note: If the extra vessels used in a transplant procedure are procured from a tissue processing organization, they are not reported in UNet.

Procedure Type: The procedure type, reported in the Recipient Feedback, will display. Verify the information displayed in the Procedure Type field is correct.

Pancreas segment
Whole pancreas with duodenum
Whole pancreas with duodenal patch
Whole pancreas

Surgical Information:

If a simultaneous Tx with another organ, was the Pancreas revascularized before or after other organs? Indicate if the pancreas was revascularized. If this surgery did not include a simultaneous transplant with another organ, select **Not Applicable**. This field is optional.

Before
Simultaneous
After
Not Applicable

Surgical Incision: Indicate the type of surgical incision. This field is optional.

Midline: Incision follows the midline of the abdomen.
Right
Left
Other

Graft Placement: Indicate where the graft was placed during the transplant operation.

Intra-Peritoneal: Pancreas graft placed totally within the peritoneal cavity.
Retro-Peritoneal: Pancreas graft placed totally behind the peritoneum (extra peritoneal).
Partial Intra/Retro-Peritoneal: Pancreas placed retroperitoneally with the peritoneum then opened.

Operative Technique: Indicate the type of pancreas transplant.

Pancreas Alone: The recipient only received a pancreas.
Cluster: The recipient received a pancreas with a least a whole liver. Other organs could also have been transplanted.
Multi-Organ Non-Cluster: The recipient received a pancreas with any other organ(s) excluding kidney and liver.
Pancreas After Kidney
Pancreas with Kidney Different Donor

Duct Management: Indicate the type of duct management used to manage the exocrine pancreatic functions.

Enteric with Roux-en-y: The pancreatic duct is allowed to drain into the small intestine using a Roux-en-y.
Enteric without Roux-en-y: The pancreatic duct is allowed to drain into the small intestine without using a Roux-en-y.
Cystostomy: The pancreatic duct is allowed to drain into the bladder.
Duct Injection Immediate: A synthetic polymer is injected directly into the pancreatic duct immediately after surgical revascularization.
Duct Injection Delayed: The duct is left open for a period up to 30 days before a synthetic polymer is injected directly into the pancreatic duct.
Other Specify: If a type of duct management used is not listed, select **Other** and enter the type of duct management in the space provided.

Venous Vascular Management: Indicate which venous system (systemic or portal) was used to attach the pancreas.

Systemic System (Iliac:Cava)
Portal System (Portal or Tributaries)
NA/Multi-organ cluster

Arterial Reconstruction: Indicate the type of arterial reconstruction used in the transplant operation.

Celiac Axis with Pancreas: The celiac axis remained attached to the pancreas and reconstruction of the artery was not necessary.

Y-Graft to SpA and SMA: The splenic artery (SpA) and the superior mesenteric artery (SMA) were attached via an arterial graft.

SpA Alone: The splenic artery alone.

SpA to SMA Direct: The splenic artery was anastomosed end-to-side to the superior mesenteric artery.

SpA to SMA with Interposition: The splenic artery was attached to the superior mesenteric artery with an interposition graft.

Other: If the type of arterial reconstruction is not listed, select **Other** and enter the type of reconstruction used in the space provided.

Venous Extension Graft: If a venous extension graft was used to lengthen the portal or splenic vein of the pancreas graft, select **Yes**. If not, select **No**.

Preservation Information: The preservation information for the pancreas procedure type is displayed for the recipient. Enter the **Total Pancreas Preservation Time**, in hours, for the pancreas procedure.

Total Pancreas Preservation Time (Include cold, warm and anastomotic time) is the time between cessation of blood flow in the donor and revascularization of the pancreas in the recipient. If the time is unavailable, select the appropriate status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**).

Note: Enter the time in hours and decimal parts of an hour. For example, 1 hour should be entered as "1", "1.0" or "1.00"; 1 hour and 30 minutes should be entered as "1.5" or "1.50" **not "1.30"**.

Clinical Information : Post Transplant

Pancreas Graft Status: Select the status that best describes the pancreas graft status.

Note: Select **Functioning** for the **Pancreas Graft Status** field if the patient was removed from the waiting list with a code 21, indicating the patient died during the transplant procedure.

Note: If death is indicated for the recipient, and the death was a result of some other factor unrelated to graft failure, select **Functioning**.

Functioning: The graft has sufficient function so that the recipient is **NOT** receiving any insulin or medication for blood sugar control.

Partial Function: The patient is taking some insulin, but ≤ 50% of the usual amount taken before transplant, or C-Peptide is present.

Failed: The graft has totally failed and the patient is completely dependent upon insulin or oral medication for blood sugar control.

If **Partial Function** or **Failed** is selected, indicate **Method of blood sugar control:** Check all that apply.

Insulin
Oral medication
Diet
No Treatment

Date insulin/medication resumed: If **Insulin** or **Oral medication** is selected, enter the date using the standard 8 digit numeric format of MM/DD/YYYY.

If **Failed** is selected, complete the following fields:

Date of Graft Failure Pancreas: If the pancreas graft failed, enter the date of the failure.

Note: The date of failure and the date insulin/medication was resumed should be the same, unless the patient has a previous partial graft function reported.

Pancreas Graft Removed: If the pancreas graft had been removed, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is optional.

If Yes, Date Pancreas Graft Removed: If the pancreas graft had been removed, enter the date of removal. This field is optional.

Pancreas Primary Cause of Graft Failure: Select the primary cause of graft failure. If the primary cause of graft failure is not listed, select **Other Specify** and enter the primary cause of graft failure in the space provided.

Graft/Vascular Thrombosis
Infection
Bleeding
Anastomotic Leak
Primary Non-Function
Acute Rejection
Hyperacute Rejection
Biopsy Proven Isletitis
Pacreatitis
Other Specify

Contributory causes of graft failure: For each of the causes listed, select **Yes**, **No**, or **Unk**nown to indicate whether each is a contributory cause of graft failure. Select **No** for the primary cause, since it cannot be both the primary and secondary cause of graft failure. If **Other** is selected, specify the cause in the space provided.

Pancreas Graft/Vascular Thrombosis
Pancreas Infection
Bleeding
Anastomotic Leak
Hyperacute Rejection
Pancreas Acute Rejection
Biopsy Proven Isletits
Pancreatitis
Other

Pancreas Transplant Complications: (**Not leading to graft failure.)** For each of the complications listed, indicate if the complication occurred prior to the recipient's hospital discharge. Do not select **Yes** if the complication contributed to failure of the pancreas graft.

Pancreatitis: If the recipient has been diagnosed as having pancreatitis, select **Yes**. If not, select **No**. If unknown, select **UNK**.

Anastomotic Leak: If the recipient exhibits signs and symptoms of an anastomotic leak, select **Yes**. If not, select **No**. If unknown, select **UNK**.

Abscess or Local Infection: If the recipient exhibits signs and symptoms of abscess or local infection, select **Yes**. If not, select **No**. If unknown, select **UNK**.

Other: If a complication other than those listed occurred, specify the complication in the space provided.

Did patient have any acute rejection episodes between transplant and discharge: If the recipient had any acute rejection episodes between transplant and discharge, select a **Yes** choice. If not, select **No**. If a **Yes** choice is selected, then indicate if a biopsy was done to confirm acute rejection.

Yes, at least one episode treated with anti-rejection agent
Yes, none treated with additional anti-rejection agent
No

Was Biopsy done to confirm acute rejection: If the recipient had an acute kidney rejection episode, indicate whether biopsy confirmed acute rejection by selecting **Yes**. If a biopsy was not done, select **Biopsy not done**. If unknown, select **Unknown**. This field is optional.

Biopsy not done
Yes, rejection confirmed
Yes, rejection not confirmed

Treatment

Biological or Anti-viral Therapy: If biological or anti-viral therapy is being administered to the recipient, select **Yes**. If not, select **No**. If unknown or can't disclose, select **Unknown/Cannot Disclose**. If **Yes** is selected, check all that apply. If a therapy, other than those listed, was administered, select **Other, Specify** and enter the therapy in the space provided. These fields are optional.

Acyclovir (Zovirax)
Cytogam (CMV)
Gamimune
Gammagard
Ganciclovir (Cytovene)
Valgancyclovir (Valcyte)
HBIG (Hepatitis B Immune Globulin)
Flu Vaccine (Influenza Virus)
Lamivudine (Epivir) (for treatment of Hepatitis B)
Valacyclovir (Valtrex)
Other, Specify

Other Therapies: If the recipient received other therapies, select **Yes**. If not, select **No**. If **Yes** is selected, check all that apply. These fields are optional.

Photopheresis
Plasmapheresis
Total Lymphoid Irradiation (TLI)

Note: If the recipient was removed from the waiting list with a code 21, indicating the recipient died during the transplant procedure, select **No** for all Biologicals or Anti-viral.

Immunosuppressive Information

Are any medications given currently for maintenance or anti-rejection: If medications have been given to the recipient for maintenance or anti-rejection during the time between transplant and hospital discharge, or 6 weeks post-transplant if the recipient has not been discharged, select **Yes**. If not, select **No**. If **Yes**, complete the sections below.

Did the recipient participate in any clinical research protocol for immunosuppressive medications: If the recipient participated in clinical research for immunosuppressive medications, select **Yes**. If not, select **No**. If **Yes**, specify in the space provided. These fields are optional.

Immunosuppressive Medications

For each of the immunosuppressive medications listed, select **Ind. (Induction)**, **Maint (Maintenance)** or **AR (Anti-rejection)** to indicate all medications that were prescribed for the recipient during the initial transplant hospitalization period, and for what reason. If a medication was not given, leave the associated box blank.

Induction (Ind.) immunosuppression includes all medications given for a short finite period in the perioperative period for the purpose of preventing acute rejection. Though the drugs may be continued after discharge for the first 30 days after transplant, it will not be used long-term for immunosuppressive maintenance. Induction agents are usually polyclonal, monoclonal, or IL-2 receptor antibodies (e.g., Methylprednisolone, Atgam, Thymoglobulin, OKT3, Simulect, or Zenapax). Some of these drugs might be used for another finite period for rejection therapy and would be recorded as rejection therapy if used for this reason. For each induction medication indicated, enter the total number of days the drug was actually administered in the space provided. For example, if Simulect or Zenapax was given in 2 doses a week apart then the total number of days would be 2, even if the second dose was given after the patient was discharged.

Maintenance (Maint) includes all immunosuppressive medications given before, during or after transplant for varying periods of time which may be either long-term or intermediate term with a tapering of the dosage until the drug is either eliminated or replaced by another long-term maintenance drug (e.g., Prednisone, Cyclosporine, Tacrolimus, Mycophenolate Mofetil, Azathioprine, or Rapamycin). This does not include any immunosuppressive medications given to treat rejection episodes, or for induction.

Anti-rejection (AR) immunosuppression includes all immunosuppressive medications given for the purpose of treating an acute rejection episode during the initial post-transplant period or during a specific follow-up period, usually up to 30 days after the diagnosis of acute rejection (e.g., Methylprednisolone, Atgam, OKT3, or Thymoglobulin). When switching maintenance drugs (e.g., from Tacrolimus to Cyclosporine; or from Mycophenolate Mofetil to Azathioprine) because of rejection, the drugs should not be listed under AR immunosuppression, but should be listed under maintenance immunosuppression.

Note: As further clarification, drugs that are used with the intention to maintain recipients long-term are medications such as Tacrolimus, Cyclosporine, Azathioprine, Mycophenolate Mofetil and Prednisone. These maintenance medications should not be listed as AR medications to treat acute rejection. When patients have a true acute rejection, they are given anti-rejection medication such as steroids, OKT3, ATG, Simulect and Zenapax, in addition to the maintenance medications. These are the medications that should be selected as anti-rejection.

If an immunosuppressive medication other than those listed is being administered (e.g., new monoclonal antibodies), select **Ind.**, **Maint**, or **AR** next to **Other Immunosuppressive Medication** field, and enter the full name of the medication in the space provided. **Do not list non-immunosuppressive medications**.

If the number of days is unavailable, select the appropriate status from the applicable **Status** field (**N/A**, **Not Done**, **Missing**, **Unknown**).

Other Immunosuppressive Medications

For each of the immunosuppressive medications listed, select **Ind. (Induction)**, **Maint (Maintenance)** or **AR (Anti-rejection)** to indicate all medications that were prescribed for the recipient during the initial transplant hospitalization period, and for what reason. If a medication was not given, leave the associated box blank.

Induction (Ind.) immunosuppression includes all medications given for a short finite period in the perioperative period for the purpose of preventing acute rejection. Though the drugs may be continued after discharge for the first 30 days after transplant, it will not be used long-term for immunosuppressive maintenance. Induction agents are usually polyclonal, monoclonal, or IL-2 receptor antibodies (e.g., Methylprednisolone, Atgam, Thymoglobulin, OKT3, Simulect, or Zenapax). Some of these drugs might be used for another finite period for rejection therapy and would be recorded as rejection therapy if used for this reason. For each induction medication indicated, enter the total number of days the drug was actually administered in the space provided. For example, if Simulect or Zenapax was given in 2 doses a week apart then the total number of days would be 2, even if the second dose was given after the patient was discharged.

Maintenance (Maint) includes all immunosuppressive medications given before, during or after transplant for varying periods of time which may be either long-term or intermediate term with a tapering of the dosage until the drug is either eliminated or replaced by another long-term maintenance drug (e.g., Prednisone, Cyclosporine, Tacrolimus, Mycophenolate Mofetil, Azathioprine, or Rapamycin). This does not include any immunosuppressive medications given to treat rejection episodes, or for induction.

Anti-rejection (AR) immunosuppression includes all immunosuppressive medications given for the purpose of treating an acute rejection episode during the initial post-transplant period or during a specific follow-up period, usually up to 30 days after the diagnosis of acute rejection (e.g., Methylprednisolone, Atgam, OKT3, or Thymoglobulin). When switching maintenance drugs (e.g., from Tacrolimus to Cyclosporine; or from Mycophenolate Mofetil to Azathioprine) because of rejection, the drugs should not be listed under AR immunosuppression, but should be listed under maintenance immunosuppression.

Note: As further clarification, drugs that are used with the intention to maintain recipients long-term are medications such as Tacrolimus, Cyclosporine, Azathioprine, Mycophenolate Mofetil and Prednisone. These maintenance medications should not be listed as AR medications to treat acute rejection. When patients have a true acute rejection, they are given anti-rejection medication such as steroids, OKT3, ATG, Simulect and Zenapax, in addition to the maintenance medications. These are the medications that should be selected as anti-rejection.

If an immunosuppressive medication other than those listed is being administered (e.g., new monoclonal antibodies), select **Ind.**, **Maint**, or **AR** next to **Other Immunosuppressive Medication** field, and enter the full name of the medication in the space provided. **Do not list non-immunosuppressive medications**.

If the number of days is unavailable, select the appropriate status from the applicable **Status** field (**N/A**, **Not Done**, **Missing**, **Unknown**).

Investigational Immunosuppressive Medications

For each of the immunosuppressive medications listed, select **Ind. (Induction)**, **Maint (Maintenance)** or **AR (Anti-rejection)** to indicate all medications that were prescribed for the recipient during the initial transplant hospitalization period, and for what reason. If a medication was not given, leave the associated box blank.

Induction (Ind.) immunosuppression includes all medications given for a short finite period in the perioperative period for the purpose of preventing acute rejection. Though the drugs may be continued after discharge for the first 30 days after transplant, it will not be used long-term for immunosuppressive maintenance. Induction agents are usually polyclonal, monoclonal, or IL-2 receptor antibodies (example: Methylprednisolone, Atgam, Thymoglobulin, OKT3, Simulect, or Zenapax). Some of these drugs might be used for another finite period for rejection therapy and would be recorded as rejection therapy if used for this reason. For each induction medication indicated, enter the total number of days the drug was actually administered in the space provided. For example, if Simulect or Zenapax was given in 2 doses a week apart then the total number of days would be 2, even if the second dose was given after the patient was discharged.

Maintenance (Maint) includes all immunosuppressive medications given before, during or after transplant for varying periods of time which may be either long-term or intermediate term with a tapering of the dosage until the drug is either eliminated or replaced by another long-term maintenance drug (e.g., Prednisone, Cyclosporine, Tacrolimus, Mycophenolate Mofetil, Azathioprine, or Rapamycin). This does not include any immunosuppressive medications given to treat rejection episodes, or for induction.

Anti-rejection (AR) immunosuppression includes all immunosuppressive medications given for the purpose of treating an acute rejection episode during the initial post-transplant period or during a specific follow-up period, usually up to 30 days after the diagnosis of acute rejection (example: Methylprednisolone, Atgam, OKT3, or Thymoglobulin). When switching maintenance drugs (example: from Tacrolimus to Cyclosporine; or from Mycophenolate Mofetil to Azathioprine) because of rejection, the drugs should not be listed

under AR immunosuppression, but should be listed under maintenance immunosuppression.

Note: As further clarification, drugs that are used with the intention to maintain recipients long-term are medications such as Tacrolimus, Cyclosporine, Azathioprine, Mycophenolate Mofetil and Prednisone. These maintenance medications should not be listed as AR medications to treat acute rejection. When patients have a true acute rejection, they are given anti-rejection medication such as steroids, OKT3, ATG, Simulect and Zenapax, in addition to the maintenance medications. These are the medications that should be selected as anti-rejection.

If an immunosuppressive medication other than those listed is being administered (e.g., new monoclonal antibodies), select **Ind.**, **Maint**, or **AR** next to **Other Immunosuppressive Medication** field, and enter the full name of the medication in the space provided. **Do not list non-immunosuppressive medications**.

If the number of days is unavailable, select the appropriate status from the applicable **Status** field (**N/A**, **Not Done**, **Missing**, **Unknown**).

Drug Codes

Sandimmune (Cyclosporine A)
Neoral (CyA-NOF)
Tacrolimus (Prograf, FK506)
Sirolimus (RAPA, Rapamycin, Rapamune)
Leflunomide (LFL, Arava)
Azathioprine (AZA, Imuran)
Mycophenolate Mofetil (MMF, Cellcept, RS61443)
Cyclophosphamide (Cytoxan)
Methotrexate (Folex, PFS, Mexate-AQ, Rheumatrex)
Atgam (ATG)
OKT3 (Orthoclone, Muromonab)
Thymoglobulin
Zenapax - Daclizumab
Simulect - Basiliximab
Gengraf (Abbott Cyclosporine)
Everolimus (RAD, Certican)
EON (Generic Cyclosporine)
Myfortic (Mycophenolate Sodium)
Other generic Cyclosporine, specify brand:
Steroids (Prednisone,Methylprednisolone,Solumedrol,Medrol,Decadron)
Campath - Alemtuzumab (anti-CD52)
FTY 720
Rituximab
Modified Release Tacrolimus FK506E (MR4)
Other Immunosuppressive Medication, Specify
Other Immunosuppressive Medication, Specify